

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134		DATE(S) OF INSPECTION 5/21/2025-5/22/2025 FEI NUMBER 3013453154	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dr. Jody R. Thompson, Laboratory Director			
FIRM NAME Sanford Clinic North		STREET ADDRESS 5225 23rd Ave S	
CITY, STATE, ZIP CODE, COUNTRY Fargo, ND 58104-7927		TYPE ESTABLISHMENT INSPECTED Hospital Blood Bank	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 A thorough investigation of each reported adverse reaction was not made. Specifically, platelet unit W042525017167 was transfused on 3/9/2025, and red cell unit W042525010625 was transfused on 4/14/2025. According to your records, recipient body temperature (b)(4) during both transfusions. No (b)(4) was performed. Your written procedure states that (b)(4) contamination is suspected when the patient experiences (b)(4) rise in temperature during the transfusion, and a (b)(4) stain with culture must be conducted on the administration (b)(4) and remaining unit.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Emily A Walters, Investigator Emily A Walters Investigator Signed by: EMILY A. WALTERS - S Date Signed: 05-22-2025 17:30:34 X	
		DATE ISSUED 5/22/2025	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."